

Attorney Docket No.: 068800-0277860

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

REVELL *et al.*

Appln. No.: 09/673,139

Filed: June 12, 2001

Title: BONE IMPLANT

Conf. No. 9561

Group Art Unit: 3732

Examiner: E.C. Robert

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APPLICANT'S INTERVIEW SUMMARY OF THE INTERVIEW OF  
JULY 22, 2004, PURSUANT TO 37 C.F.R 1.133(b)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. 1.133(b), the substance of the telephone interview held on July 22, 2004, between examiner Eduardo C. Robert of the U.S.P.T.O. and Charles C. P. Rories, Ph.D., on behalf of the applicants, is described below.

(1) A copy of the draft response attached hereto as an appendix was forwarded to the examiner via facsimile on July 21, 2004, to use as a reference in the telephone interview.

(2) In the telephone interview, Dr. Rories directed the examiner's attention to the proposed amendments of independent claims 1 and 15 in the draft response. As proposed, both amended claims would specify that the bioactive material promotes bone growth onto the bone implant, and that ions of one or more of the groups of the periodic table consisting of groups IIA, IVA, VIIA and transition elements are incorporated (i) up to a maximum depth of 200 nm into the surface; and (ii) at a level whereby ongrowth onto the implant is enhanced as compared with unmodified bioactive material.

(3) Referring to the printed remarks stated in the draft response shown in the appendix, Dr. Rories argued that the rejections of claims under 35 U.S.C. §103(a) as being obvious in

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view of either U.S. Patent No. 5,817,326 of Nastasi et al. (hereinafter "Nastasi") or U.S. Patent No. 5,188,670 of Constantz et al. (hereinafter "Constantz") should be withdrawn for the reasons stated therein.

In particular, Dr. Rories stated that the inventors believe that the ions of the present invention do not form a coating of the bioactive surface, but become located in the interstices just at the surface of the bioactive coating. The increase in bone ongrowth onto the bioactive material and the increased mechanical bonding of the bioactive coating that results from this incorporation was described as a **surprising result that was not predicted by the prior art.**

Dr. Rories pointed out to the examiner that both prior art documents are concerned with producing layered hydroxyapatite coatings, and with treatments of metal or hydroxyapatite surfaces that promote the bonding of hydroxyapatite layers to one another and to the underlying metal of the implant. In contrast, the present invention was described as being concerned with an enhancement of bioactivity of the hydroxyapatite coating of the coated implant.

Further with respect to Nastasi, Dr. Rories directed the examiner's attention to col 5, lines 9-10, of the Nastasi patent, which taught that "the total coating thickness would optimally be between 50 and 200  $\mu\text{m}$ ." It was argued that the claimed invention would not have been obvious to one of ordinary skill in the art in view of Nastasi, because the recommendation in Nastasi of the use of a coating of 50,000 to 200,000 nm in thickness would have taught away from the claimed invention, in which the ions are incorporated up to a maximum depth of 200 nm into the surface.

Further with respect to Constantz, Dr. Rories argued that Constantz was concerned only with wet chemistry and did not disclose ion beam implantation; and that the methods used in Constantz would not have achieved the interstitial incorporation of atoms or ions in the first 200 nm at the surface of a bioactive hydroxyapatite coating as required by the present invention. In addition, it was pointed out that in column 3, lines 49 to 51, Constantz indicated that the total thickness of the second and succeeding layers would be in the range of 5  $\mu\text{m}$  to 20  $\mu\text{m}$  (5,000 nm to 20,000 nm), which, like Nastasi, would have taught away from the claimed invention, in which the ions are incorporated up to a maximum depth of 200 nm into the surface.

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The examiner kindly stated that the applicants' arguments would be given full consideration, but that they were generally unpersuasive for the reasons stated in the previous office action.

The examiner further stated that the claimed invention includes deposition of ions on the surface, where they could technically be considered a "coating." In response, Dr. Rories noted that the ions of the invention are dispersed and would not form a continuous layer such as the "coatings" of the prior art.

The examiner also pointed to the paragraph bridging pages 3 and 4, where it is stated that "[w]hilst this [200 nm] is the preferred maximum depth of ions, it is possible to implant ions to greater depths, for example, 1000 nm," and he argued that the 200 nm maximum depth is therefore not considered to be a "critical" feature. In response to the latter argument, Dr. Rories reminded the examiner that under 35 U.S.C. §103(a), the invention that is described in the claims is the invention for which obviousness must be considered.

Dr. Rories concluded the interview by thanking the examiner for agreeing to participate in the interview and for considering the applicants' arguments in favor of the allowability of the claims.

Respectfully submitted,  
PILLSBURY WINTHROP, LLP

By Charles C. P. Rories  
Charles C. P. Rories, Ph.D.  
Reg. No.: 43,381  
Tel. No.: (703) 905-2137  
Fax No.: (703) 905-2500

PILLSBURY WINTHROP LLP  
P.O. Box 10500  
McLean, VA 22102